REMARKS

Interview request

Applicants also respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

Status of the Claims

Pending claims

Claims 1 to 23, 25 to 32 and 34 to 79 are pending (see preliminary amendment filed September 26, 2003).

The Group Restriction Requirement

The Patent Office alleged that the pending claims of the application are directed to two separate and distinct inventions under 35 U.S.C. §121 (see sections A and B, page 2, of the OA):

> Group I: Claims 1 to 23, 25 to 32, 34 to 41 and 75 to 79, drawn to chimeric polypeptides, fusion proteins, nucleic acids encoding the chimeric polypeptides and/or fusion proteins of the invention, compositions and kits comprising chimeric polypeptides and/or fusion proteins, or nucleic acids, of the invention, classified in class 530, subclass 350; and, class 425, subclass 69.1.
>
> Group II: Claims 1 to 23, 25 to 32, 34 to 41 and 75 to 79, drawn to use of a chimeric polypeptide and/or fusion protein of the invention to prepare a pharmaceutical composition, and methods of treating a disease with the composition, classified in class 514, subclass 2.

The Group Election

In response to the Restriction Requirement, Applicants elect Group I, claims 1 to 23, 25 to 32, 34 to 41 and 75 to 79, with traverse.

Applicants respectfully request that, after the elected product claims have been found to be allowable, all withdrawn process (methods) claims which depend from or otherwise include all of the limitations of the allowed product claims be rejoined. MPEP §821.04; pg 800-63, 8th Edition, August 2001; In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995); In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1995); 1184 OG 86, 3/26/96.

The SubGroup Restriction Requirement

The Patent Office also alleged that the pending claims of Group I are drawn to a number of structurally distinct and non-overlapping chimeric proteins and fusion proteins with binding affinity for distinct ligand, and thus are directed to separate and distinct inventions under 35 U.S.C. §121 (see section C, pages 2 to 3, of the OA):

SubGroups:

1. a specific binding affinity for a first polypeptide domain, selected from CCR5, CXCR3, CCR4, CCR6, CCR10, CXCR4, CCR1, CCR2, CCR3, CCR7, CCR8, CCR9, XCR1 or CX3CR1.

(i) (if CCR5 is elected), a chemokine peptide selected from RANTES, MIP-1a (MIP-1α), MIP-1b (MIP-1β), MCP-2, or MCP-3, or the bispecific antibody defined by SEQ ID NO:18.

2. a second polypeptide domain selected from a moiety that specifically binds CD3, or binds a toxin selected from *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin or diptheria toxin; or a second moiety that is a toxin selected from *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin or diptheria toxin.

The SubGroup Elections

In response to the Subgroup Restriction Requirement, Applicants elect, with traverse:

SubGroups:

1. a specific binding affinity for CCR5.

(i) the bispecific antibody defined by SEQ ID NO:18.

2. a second polypeptide domain that specifically binds CD3.

Reasons to reconsider and withdraw restriction requirement

Applicants respectfully request the Patent Office reconsider and, in part, withdraw the group restriction requirement for the following reasons:

Group I and Group II

Applicants respectfully request that the claims of Group II be re-joined to the elected Group I because, inter alia, the two groups share a common inventive concept and a thorough search of

Group I would necessarily encompass the same thorough search needed for the claimed invention of Group II.

Applicants respectfully aver that after a complete search directed to Group I's chimeric polypeptides, fusion proteins, nucleic acids encoding the chimeric polypeptides and/or fusion proteins of the invention, compositions and kits comprising chimeric polypeptides and/or fusion proteins, or nucleic acids, of the invention, it would not be an undue burden for the Patent Office to also do a complete search for Group II's chimeric polypeptides and fusion proteins of the invention to prepare a pharmaceutical composition and methods of treating a disease with the composition.

Furthermore, Group I and Group II share common inventive concept comprising a chimeric polypeptide of the invention directed against CCR5 and CD3.

Accordingly, Applicants respectfully request the Patent Office to rejoin all claims directed to dietary aids and other compositions comprising phytases and their corresponding methods of use into one restriction group.

SubGroup Rejoining

Applicants respectfully request that all the exemplary chemokine receptors for a first polypeptide domain, including CCR5, CXCR3, CCR4, CCR6, CCR10, CXCR4, CCR1, CCR2, CCR3, CCR7, CCR8, CCR9, XCR1 and CX3CR1, be joined into a generic group drawn to chimeric polypeptides comprising, inter alia, a first polypeptide domain comprising at least one moiety that specifically binds to a chemokine receptor.

Applicants respectfully request that all the exemplary moieties that specifically bind to a chemokine receptor, including chemokine peptides RANTES, MIP-1a (MIP-1α), MIP-1b (MIP-1β), MCP-2, or MCP-3, or the bispecific antibody defined by SEQ ID NO:18, be joined into a generic group drawn to chimeric polypeptides comprising, inter alia, a first polypeptide domain comprising at least one moiety that specifically binds to a chemokine receptor.

Applicants respectfully request that all the exemplary toxins, including *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin or diptheria toxin; or a second moiety that is a toxin selected from *Pseudomonas* PE38 exotoxin, PE40 exotoxin, PE37 exotoxin or diptheria toxin, be joined into a generic group drawn to chimeric polypeptides comprising, inter alia, a first polypeptide domain comprising at least one moiety that specifically binds to a chemokine receptor; and, a

second polypeptide domain comprising at least one moiety that specifically binds to a T cell surface polypeptide or a cell toxin, or, comprising a cell toxin.

In particular, Applicants respectfully request that the restriction requirement with respect to these subgroups be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a).

If the instant group restriction requirement is allowed to stand, Applicants will not be allowed to claim their invention as they choose. If the elected invention is limited to only specific members of any of the listed subgroups (chemokine receptors, or "specific binding affinities for the first polypeptide domain" (subgroup 1); chemokine peptides (subgroup 1(i)); or toxins (subgroup 2)), the full scope of the genus of the claimed invention would never be examined. Even if Applicants filed divisional applications to all these subgroups, the scope of the genus of chemokine receptors, chemokine peptides or toxins in the pending claimed invention would never be examined. In other words, if the pending claims of Group I are required to be divided up and presented in different divisional applications, the full scope of the instant pending claims of Group I would never be considered on its merits. The totality of the resulting fragmentary claims would not be the equivalent of the original claims of Group I.

The procedure for handling applications that include generic claims is set forth in 37 CFR §1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable."

As stated in MPEP §809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable (emphasis added). MPEP §809.02(a); pg 800-52 to 800-53, 8th Edition, rev. 3, August 2005.

In the instant restriction requirement, this required procedure is not being followed. The independent claims of Group I are proper generic claims within the requirements set forth in 37 CFR § 1.141. The independent claims of Group I each satisfy the definition of a generic claim as set forth in MPEP §806.04(d), in that each includes limitations that are not present in all claims that depend from it. Therefore, an election of species requirement is permissible, but a restriction requirement is not (MPEP §806.04(d), pg 800-42 to 800-43, 8th Edition, rev. 3, August 2005).

Moreover, because this restriction requirement splits the independent claims of Group I into multiple groups, the restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority for not examining a broad generic claim. See, In re Weber, 198 USPQ 328, 331 (CCPA 1978); In re Haas, 179 USPQ 623, 624-625 (*In re Haas I*) (CCPA 1973) and In re Haas 198 USPQ 334-337 (In re Haas II) (CCPA 1978). As stated in In re Weber:

> "The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it." 198 USPQ 328 at 334.

In a case such as the instant case, where a claim is generic, a restriction requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in In re Haas I:

> "We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained." 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will not be accorded "the basic right of the applicant to claim his invention as he chooses." In re Weber, 198 USPQ at 331. In In re Weber, the CCPA stated that "[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits" (198 USPQ at 331, emphasis in original). The Court went on to state that:

> "If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." 198 USPQ at 331.

Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. MPEP §803.02, pg 800-4 to 800-5, 8th Edition, rev. 3, August 2005. Even if Applicants were to file multiple divisional applications in addition to the instant application to obtain coverage for each of the alleged subgroups, Applicants would not have the opportunity to have their broader generic claim examined, i.e., Applicants would not have the opportunity to have that which they regard as their invention examined. The claims of the divisional applications would be limited to the particular exemplary species of each subgroup (a single exemplary chemokine receptor, or exemplary "specific binding affinity for the first polypeptide domain" (subgroup 1); a single exemplary chemokine peptide (subgroup 1(i)); or a single exemplary toxin (subgroup 2)). One seeking to avoid infringement could simply choose an alternative specie within the scope of the genus that is not specifically claimed in any particular (divisional) application. In effect, the restriction requirement is reading into Applicants' independent claims limitations that are not present in the claims as filed. The independent claims of Group I as filed and pending, for example, would never be considered, and thus never allowed, under the current restriction requirement. Only the dependent claims which are set forth in the respective restriction groups would be examined.

Applicants therefore respectfully request that the instant restriction requirement with respect to all the subgroups be withdrawn (and rejoined as a generic restriction) and treated as though it were a species election under the procedure set forth in MPEP 809.02(a).

Pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the restriction requirement at any time prior to appeal. Applicants also submit that because the instant restriction requirement is tantamount to a rejection of the generic claim 1, the restriction

requirement is appealable to the Board of Patent Appeals and Interferences. In re Haas I. If the instant restriction requirement is allowed to stand, Applicants will not be accorded "the basic right of the applicant to claim his invention as he chooses." In re Weber. It is improper for the Office to refuse to examine that which Applicants regard as their invention. MPEP §803.02, pg 800-4 to 800-5, 8th Edition, rev. 3, August 2005.

Accordingly, Applicants respectfully request reconsideration of the group restriction requirement and request that the restriction requirement with respect to Groups I and II be withdrawn. Applicants also respectfully request reconsideration of the subgroup restriction requirement and request that this subgroup restriction requirement be treated as a species election under the procedure set forth in MPEP 809.02(a); in other words, Applicants request that the subgroup restriction requirement with respect to the claimed genus of chemokine receptors ("binding affinities"), chemokine peptides and toxins be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a).

CONCLUSION

Applicants have elected the invention of Group I, with traverse, for reasons stated above. Applicants have elected the invention of Subgroups: 1. a specific binding affinity for CCR5; (i) the bispecific antibody defined by SEQ ID NO:18; and, 2. a second polypeptide domain that specifically binds CD3, with traverse, for reasons stated above.

Thus, in this response Applicants traversed the group restriction requirement and respectfully requested the restriction be withdrawn, in part, as discussed above. Applicants set forth distinct and specific errors in the Group and SubGroup restriction requirement and reasons for the Patent Office to reconsider and withdraw, in part, the Group and SubGroup restriction requirement. Applicants have also requested that the SubGroup restriction requirement be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a). Accordingly, Applicants have preserved their right to petition the restriction to the Group Director under 37 CFR §1.144; see also MPEP §818.03(c); pg 800-60, 8th Edition, rev. 3, Aug. 2005. Applicants will defer submission of the petition (which can be deferred until allowance of the claims).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 577782000101. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 7205133.

Dated: July 31, 2006

Respectfully submitted,

By

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